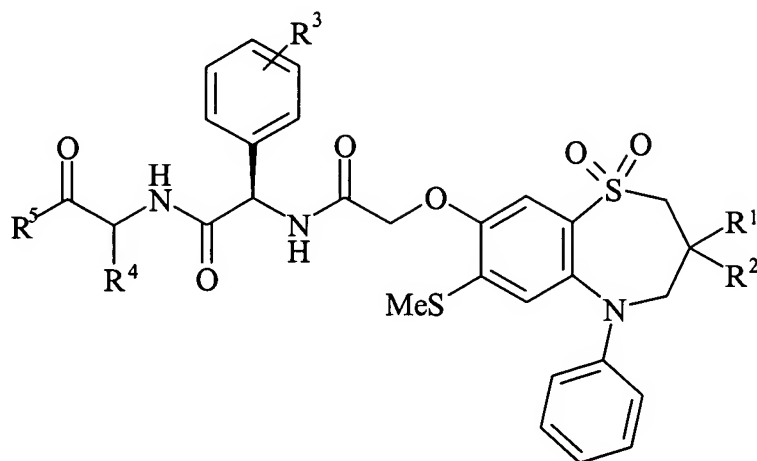


Claim 1 (currently amended): A compound of formula (I):



(I)

~~**R¹** and **R²** are both butyl-independently selected from C₁₋₄alkyl;~~

R⁴ is C₁₋₄alkyl optionally substituted by hydroxy, methoxy and methylS(O)_a wherein

R⁶ is selected from hydrogen and C₁₋₃alkyl optionally substituted by hydroxy, cyano and methylS(O)_a wherein a is 0-2;

or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof;

with the proviso that when R¹ and R² are both butyl, R⁵ is hydroxy and R⁴ is methylthiomethyl, methylsulphinylmethyl, 2-methylthioethyl, hydroxymethyl, methoxymethyl; R³ is not hydrogen; and with the proviso that when R¹ and R² are both butyl, R⁵ is HOC(O)CH(R⁶)NH-, R⁶ is hydroxymethyl and R⁴ is hydroxymethyl; R³ is not hydrogen.

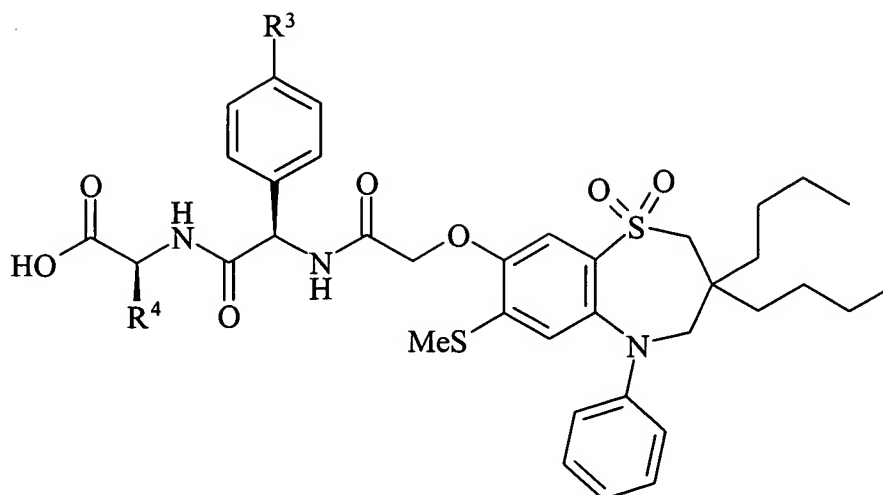
Claims 2-3 (cancelled).

Claim 4 (**currently amended**): A compound of formula (I) according to claim 1 ~~any one of claims 1 to 3~~ wherein R³ is hydrogen or hydroxy; or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof.

Claim 5 (**currently amended**): A compound of formula (I) according to claim 1 ~~any one of claims 1 to 4~~ wherein R⁴ is selected from methyl and ethyl; or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof.

Claim 6 (**currently amended**): A compound of formula (I) according to claim 1 ~~any one of claims 1 to 5~~ wherein R⁵ is hydroxy; or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof.

Claim 7 (**currently amended**): A compound of formula (I'):



(I')

wherein:

R^4 is selected from C_{1-4} alkyl, hydroxymethyl, 1-hydroxyethyl, methoxymethyl, methylthiomethyl, methylsulphinylmethyl, mesylmethyl, 2-methylthioethyl, 2-methylsulphinylethyl and 2-mesylethyl and R^3 is hydroxy; or

R^4 is selected from C_{1-4} alkyl, 1-hydroxyethyl, mesylmethyl, 2-methylsulphinylethyl and 2-mesylethyl and R^3 is hydrogen;

or a pharmaceutically acceptable salt, solvate, or solvate of such a salt ~~or a prodrug~~, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof.

Claim 8 (**currently amended**): A compound of formula (I) as claimed in claim 1 selected from:

- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxyethyl) carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxypropyl) carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxybutyl) carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-

methylpropyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-methylbutyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-methylbutyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-hydroxypropyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-mesylethyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

~~1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-methylsulphonylpropyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;~~

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-mesylpropyl)carbamoyl]benzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxyethyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxypropyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxybutyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-methylpropyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-methylbutyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-methylbutyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-hydroxyethyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-hydroxypropyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-methylthioethyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-methylsulphinyethyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-mesyethyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-2-methoxyethyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;
- 1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-methylthiopropyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-

1,5-benzothiazepine;

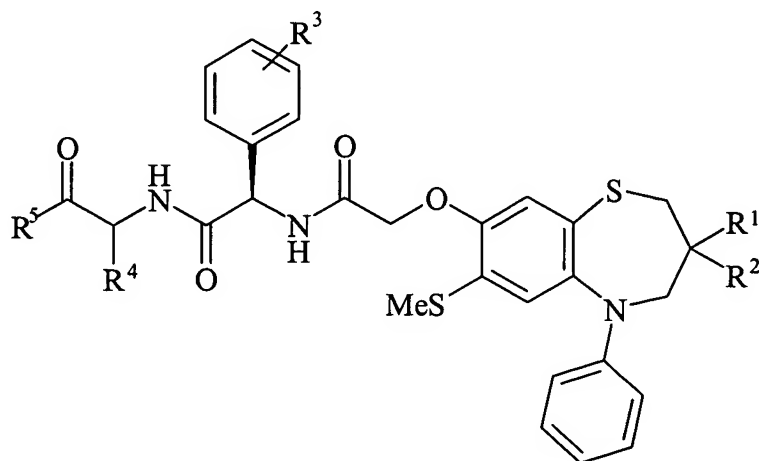
1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-methylsulphinylpropyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

1,1-dioxo-3,3-dibutyl-5-phenyl-7-methylthio-8-(*N*-{(*R*)- α -[*N'*-((*S*)-1-carboxy-3-methylsulphinylpropyl)carbamoyl]-4-hydroxybenzyl} carbamoylmethoxy)-2,3,4,5-tetrahydro-1,5-benzothiazepine;

or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof.

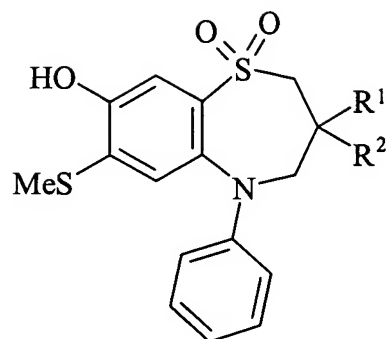
Claim 9 (**currently amended**): A process for preparing a compound of formula (I) as claimed in claim 1 or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof which process (wherein variable groups are, unless otherwise specified, as defined in formula (I)) comprises of:

Process 1): oxidising a benzothiazepine of formula (II):



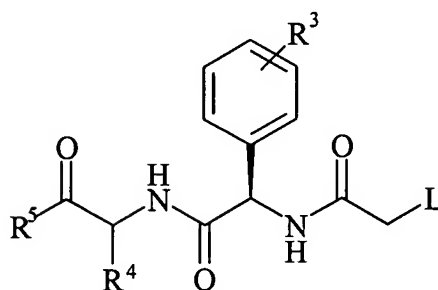
(II);

Process 2): reacting a compound of formula (III):



(III)

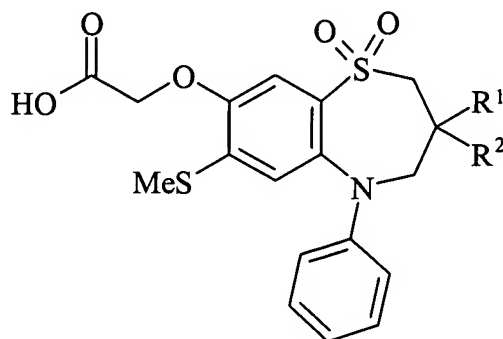
with a compound of formula (IV):



(IV)

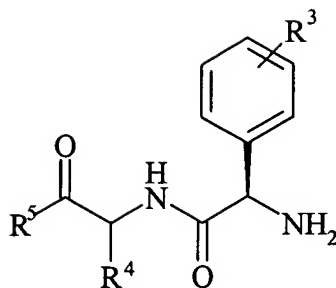
wherein L is a displaceable group;

Process 3): reacting an acid of formula (V):



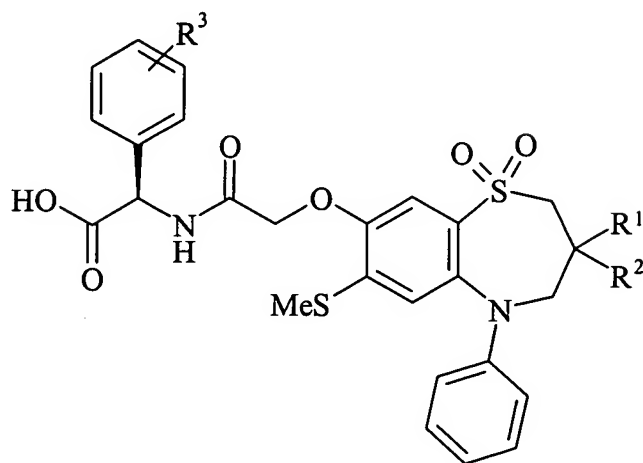
(V)

or an activated derivative thereof; with an amine of formula (VI):



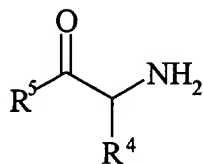
(VI);

Process 4): reacting an acid of formula (VII):



(VII)

or an activated derivative thereof; with an amine of formula (VIII):



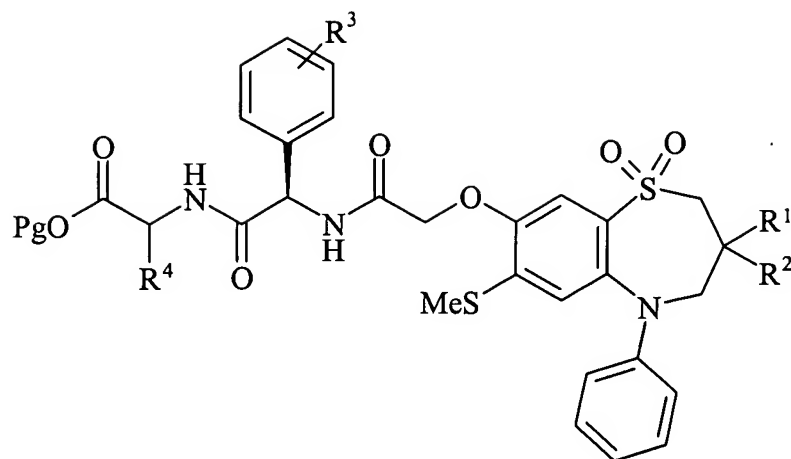
(VIII)

Process 5): for compounds of formula (I) wherein R⁵ is HOC(O)CH(R⁶)NH₂-; reacting a compound of formula (I) wherein R⁵ is hydroxy with an amine of formula (IX):

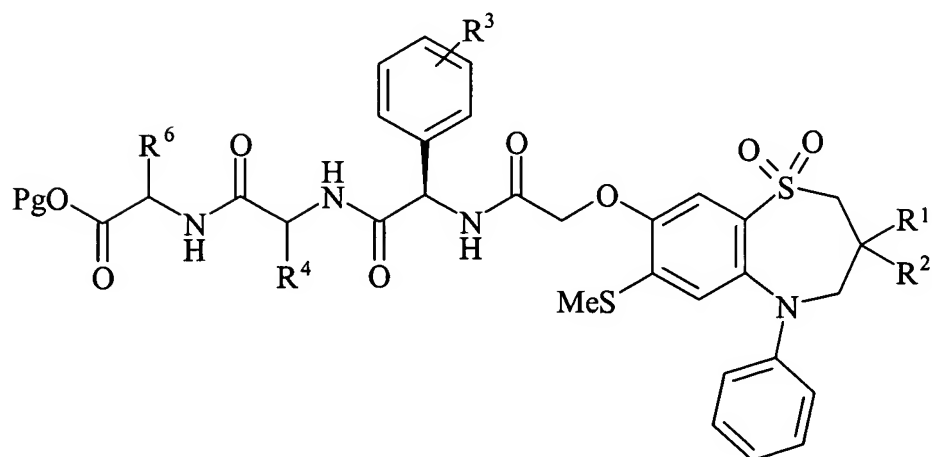


(IX)

Process 6): deprotecting a compound of formula (X) or a compound of formula (XI):



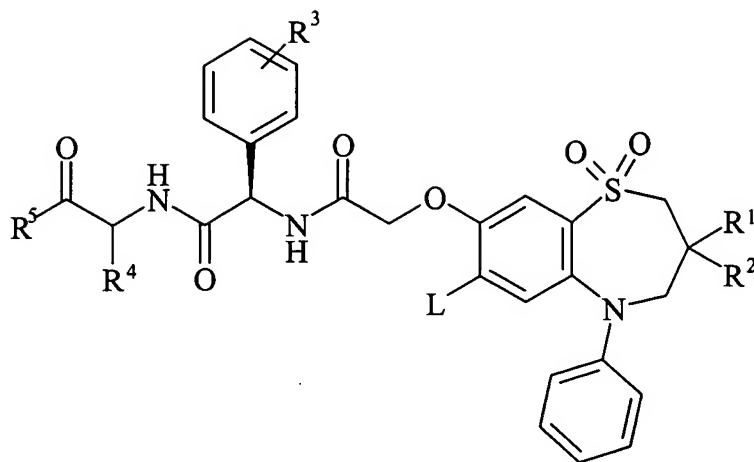
(X)



(XI)

wherein Pg is an acid protecting group;

Process 7) reacting a compound of formula (XII):



(XII)

wherein L is a displaceable group; with methylthiol;

and thereafter optionally if necessary or desirable:

- i) converting a compound of the formula (I) into another compound of the formula (I);
- ii) removing any protecting groups;
- iii) forming a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof.

Claims 10-12 (cancelled).

Claim 13 (currently amended): A method for ~~producing an inhibiting~~ IBAT ~~inhibitory effect in a warm-blooded animal, such as man, in need thereof of such treatment~~ which comprises administering to said animal an effective amount of a compound of formula (I) or formula (I'), or a pharmaceutically acceptable salt, solvate, or solvate of such a salt or a prodrug, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof, as claimed in any one of claims 1 or 4 to 8.

Claim 14 (currently amended): A pharmaceutical composition which comprises a compound of formula (I) or formula (I'), or a pharmaceutically acceptable salt, solvate, or

solvate of such a salt ~~or a prodrug~~, or an *in vivo* hydrolysable ester formed on an available carboxy or hydroxy thereof, or an *in vivo* hydrolysable amide formed on an available carboxy thereof, as claimed in any one of claims 1 or 4 to 8, in association with a pharmaceutically-acceptable diluent or carrier.

Claims 15-21 (cancelled).